

K961965

### **510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:\_\_\_\_\_.

1. **Submitter's Identification:**

Mr. Paul Reiter  
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Date Summary Prepared: May 14, 1996

2. **Name of the Device:**

Sure Check™ Pregnancy Test

3. **Predicate Device Information:**

Chembio HCG STAT-PAK, K#923925/A  
Clearblue Easy Pregnancy Test, E.P.T. Pregnancy Test

4. **Device Description:**

The Sure Check™ Pregnancy Test is a self contained immunochromatographic test designed for use in detecting hCG in urine samples. After the person wets the wick in the device the urine is absorbed and transferred to a pad where a labelled colloidal gold containing a monoclonal antibody directed against beta hCG is present. If the antigen (hCG) is present, an antigen/antibody reaction takes place forming a complex. This migrates along the nitrocellulose support to the Test Line which is printed on the membrane. This is another antibody, in this case a monoclonal anti-hCG antibody, which captures the colored complex when it passes over the immobilized test line antibody. As the complex adheres to the capture antibody a visible light to dark purple band appears indicating a positive test result. The remaining complex travels further along the membrane to another immobilized control antibody. This captures the remaining complex forming another purple band indicating that the test has been performed properly.

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**5. Intended Use:**

An OTC hCG Pregnancy Test for home use intended for the early detection of pregnancy. It is intended to measure hCG, a placental hormone, in urine sample.

**6. Comparison to Predicate Devices:**


The Sure Check™ Pregnancy Test was compared in clinical trials to the Chembio HCG STAT-PAK, K#923925/A.

The Sure Check™ Pregnancy Test is designed as a home use midstream test where the sample is added via urinating directly onto an absorbent wick. The sample is transferred to the reactive membrane via this membrane where the reactions take place as described above. The HCG STAT-PAK utilizes the same immunochromatographic principle as described in Section 4-Device Description with the exception that the sample is collected in a cup/container and added via a dropper supplied with the kit. However, aside from the method in which the sample is added to the membrane, there are no differences in the chemistry between the tests.

**7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Sure Check™ Pregnancy Test in the intended environment of use is supported by testing that was conducted in accordance with the FDA's Clinical Chemistry's "Draft-Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)," 9/27/95.

The following testing was conducted by Chembio Diagnostic Systems, Inc. personnel:

- a. Sensitivity/Detection Limit Study - Exhibit #6
  - b. Specificity Study - Exhibit #7
  - c. Interfering Substance Study - Exhibit #8
  - d. Time Study For Holding the Device in the Urine Stream - Exhibit #9
  - e. Optimal Reaction Time Study - Exhibit #10
  - f. Reproducibility Study - Exhibit #11
  - g. Linearity Study - Exhibit #12
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None of the testing demonstrated any design characteristics that deviated from the requirements of the Reviewer Guidance or resulted in any safety or effectiveness concerns.

**8. Discussion of Clinical Tests Performed:**

The Sure Check™ Pregnancy Test was compared in clinical trials to the Chembio HCG STAT-PAK. Please refer to Exhibit #3, "Comparative Study Data: Accuracy as Determined by Correlation of Proposed Device with Currently Marketed Device (Professional Use)" - "Clinical Trial Report: An Open Study to Evaluate the Ability of Sure Check™ to Determine Pregnancy" - Study Conducted and Monitored by: Target Health Inc., 310 Madison Avenue, 22nd Floor, New York, NY 10017, concluding that our device is effective in diagnosing pregnancy.

**9. Conclusions:**

Our testing demonstrated that the Sure Check™ Pregnancy Test is as safe and effective as the predicate device for the intended use of the device.

